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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,746	07/26/2001	Yajun Guo	532732000101	1834

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,746	GUO ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/4/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite in the recitation of "corresponds to". It is unclear how a first antibody which "corresponds to" a second antibody differs from said second antibody.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

Applicant's referral to the deposit the hybridoma secreting the SM5-1 antibody on page 4, lines 10-11 of the specification is s an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney or record who has the authority and control over the conditions of deposit over his/her signature or registration number stating that the deposit has been accepted by an International Depository authority under the

provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed from the depository as required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CRF 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his/her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

( ) the deposits will be maintained in a public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced should they become non-viable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Applicant's attention is directed to In re: Lundak, 773 F. 2d.1216, 227 USPQ 90 (CAFC 1985) and 37 CRF 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11, 12 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by the abstract of Chen et al (Journal of Molecular Medicine, May 1998, Vol. 76, page B11).

The specification states that the SM5-1 antibody was deposited under the Accession number HB-12588 (page 4, lines 10-11)..

The abstract of Chen et al discloses that the SM5-1 antibody was made by immunization of mice to the non-metastatic SMMUneg cell line, treatment of said mice with cyclophosphamide and subsequent immunization of the mice with a metastatic SMMUpos cell line, thus teaching how to make the hybridoma that secretes the SM5-1 antibody. The abstract discloses that the SM5-1 antibody binds to human fibronectin at the 3' end of the protein encoded by the polynucleotide at position 4500-7660. The abstract did not specifically disclose that the antibody was conjugated to a label which produces a detectable signal, however this would be inherent in the immunohistochemical analysis of the tissue samples. The abstract discloses a method for detecting the presence of melanoma in a human host comprising contacting a tissue sample with the SM5-1 monoclonal antibody and detecting the formation of immune complexes as indicative of melanoma.

Claims 1-6, 8-13 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by the abstract of Trefzer et al (Journal of Dermatological Science, March 1998, Vol. 16, suppl. 1, page S110, reference 57 of the IDS submitted October 4, 2002)..

The specific embodiments of claims 1-9, 11, 12 and 18 are set forth above. Claims 10 embodies the method of claim 9 wherein the tissue sample is paraffin-embedded or cryo-preserved.

The abstract of Trefzer et al discloses a method for detecting the presence of melanoma in a human host comprising contacting a tissue sample with the SM5-1 monoclonal antibody and

detecting the formation of immune complexes as indicative of melanoma. The abstract discloses that the SM5-1 detected melanoma in paraffin-embedded melanozytic tissues by means of the APAAP-technique for staining the tissues, thus fulfilling the specific embodiment of claim 9, drawn to a detectable label, claim 10, drawn to a paraffin-embedded tissue and claim 13 drawn to an enzyme as a detectable label.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al (Biochem Biophys Research Commun, 1981, Vol. 101, pp. 1047-1051) as evidenced by the abstract of Chen et al (Journal of Molecular Medicine, May 1998, Vol. 76, page B11)

It is noted that the abstract of Chen et al (Journal of Molecular Medicine, May 1998, Vol. 76, page B11) discloses that the SM5-1 reacted with 18 different non-melanoma cell lines grown in culture in contrast to the 22 other non-melanoma tumor types which were all negative when stained with SM5-1. The abstract concludes that the lack of selectivity with regard to non-melanoma cultured tumor cells was a result of lack of post-translational processing of the fibronectin in the melanoma tumor samples and the non-melanoma cultured cell lines. It would be expected that SM5-1 would bind to synthetic fibronectin which was devoid of post-translational processing, in addition to fibronectin expressed in cultured tumor cells, and transformed cells, and fibronectin expressed in microorganisms such as E coli and yeast.

Wilson et al disclose fibronectin from human melanoma cells which is the same as the antigen claimed.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by McCarthy et al (Biochemistry, 1988, Vol. 27, pp. 1380-1388) as evidenced by the abstract of Chen et al (Journal of Molecular Medicine, May 1998, Vol. 76, page B11).

Claim 1 is drawn to a monoclonal antibody which specifically binds an antigen on human melanoma cells wherein said antigen is specifically bound to the antibody secreted by the hybridoma of ATCC Accession No. HB-12588. Claim 2 embodies the hybridoma producing the antibody of claim 1.

The specification states that the SM5-1 antibody was deposited under the Accession number HB-12588 (page 4, lines 10-11)..

The abstract of Chen et al discloses that the SM5-1 antibody binds to fibronectin. McCarthy et al disclose the antibodies AHB-1 and AHB-2 bind to epitopes located on the carboxyl terminal chains of fibronectin which is the same as the antibodies claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarthy et al (Biochemistry, 1988, Vol. 27, pp. 1380-1388) in view of the abstract of Sekiguchi et al (Seikagaku, 1989, 61, pp. 89-93).

.McCarthy et al teach the antibodies AHB-1 and AHB-2 bind to epitopes located on the carboxyl terminal chains of fibronectin. The abstract of Chen et al discloses that the SM5-1 antibody binds to fibronectin and the specification states that the SM5-1 antibody was deposited under the Accession number HB-12588 (page 4, lines 10-11). McCarthy et al do not teach a method of detecting melanoma comprising contacting a sample with the AHB-1 and AHB-2 antibodies.

The abstract of Sekiguchi et al teach that various forms of fibronectin are associated with the transformed state and the IIICS region of fibronectin which is present on melanoma cells.

It would have been prima facie obvious at the time invention was made to use the AHB-1 and AHB-2 to detecting melanoma fibronectin on cells or in blood samples. One of skill in the art would have been motivated to do so by the teachings of Sekiguchi et al on the presence of the ED-A+ and ED-B+ fibronectin in transformed cells.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8-12 and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 36-38, 49, 50, 52-54, 63-66, 73 and 74 of copending Application No. 09/722,849. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '849 application anticipate the instant claims.

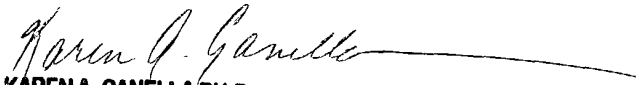
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
6/28/2004



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PRIMARY EXAMINER